

REMARKS

A Request for a One (1) Month Extension of Time pursuant to 37 CFR §1.136(a) and (b) is attached hereto.

The above-captioned patent application has been carefully reviewed in light of the non-final Office Action to which this Amendment is responsive. Claims 1, 3, 4, 6-14, 41-43, 46-48, 51-55 and 58-60 have been amended in order to further clarify and to particularly point out that which is regarded as the present invention. Claims 2, 5, 44, 50 and 57 have been canceled and new Claims 74-82 have been added. To that end, no new matter has been added.

Claims 1-73 were originally pending. Claims 15-40 and 61-73 have been withdrawn from consideration based on a Restriction Requirement which has now been made final. Acknowledgement of same is hereby made by Applicants.

The Examiner has rejected all elected Claims 1-14 and 41-60 based on certain prior art, as well as certain paragraphs of Section 112. Applicants herein respectfully request reconsideration based on the amended claims as well as the following discussion.

Turning to the prior art rejections, Applicants believe that each of the prior art rejections of Claims 1-3, 6, 7, and 41-43 under 35 USC §102(b) as being anticipated by Samsoundar (WO 99/47261), Claims 1, 2, 8 and 41 under 35 USC §102(b) as being anticipated by Corbett (WO 92/20776), Claims 4 and 53 under 35 USC §103(a) as being unpatentable over Samsoundar as applied to Claims 1, 41 and further in view of Corbett, and Claims 3, 4, 42, and 53 under 35 USC §103(a) as being unpatentable over Corbett as applied to Claims 1, 2 and 41 above are each moot in that Applicants have now added the subject matter of Claims 2 and 5 to independent Claim 1 and Claims 44 and 50 to independent Claim 41. Withdrawal of these rejections is therefore respectfully requested.

As a result, the only pending prior art rejection is that of Claims 1-60 having been rejected under 35 USC §103(a) as being unpatentable over Jacobs et al. (US Patent No. 5,846,492) in view of either Corbett and/or Samsoundar. Applicants respectfully traverse this rejection, as follows:

First, Applicants have assumed this rejection merely indicates a rejection of pending Claims 1-14 and 15-60 of the application, since Claims 15-40 have been withdrawn from prosecution due to the preceding Restriction Requirement, now made final as noted in items 1 and 2 of the outstanding Office Action. If the Examiner intends for Claims 15-40 to be included in this rejection, then withdrawal of the Restriction Requirement is respectfully requested. Therefore and for purposes of this response, Applicant has ignored the rejection of the previously withdrawn claims and herein discusses Claims 1-14 and 41-60 only.

In order to successfully maintain a "*prima facie*" obviousness rejection under the Statute, each and every each essentially claimed limitation must be found in or suggested by, either singly or in combination, the cited art. Those essentially claimed limitations that are not found in or suggested by the cited art must be notoriously well known in the field. Moreover, there must be a motivation found in the prior art as a whole at the time of the invention to make the purported combination at the time of the invention. This motivation must not be the result of impermissible hindsight (i.e., advance knowledge of the invention), but rather the entirety of each cited reference must be regarded.

Jacobs et al. describes a technique for detecting the quality of a patient sample using a sealed metering tip. According to the technique described therein, a sample is first aspirated into a metering tip. A partial pressure or vacuum is then created within the aspiration probe and the attached metering tip to draw the fluid into the tip sufficiently such that fluid profusion does not occur at the dispense end of the tip.

Jacobs et al. further illustrates a primary sample handler or supply used in conjunction with an analyzer that includes an outer ring having a plurality of sample containers and an inner periphery that includes a plurality of unsealed disposable metering tips. The sample containers contained within the outer ring of this assembly are not metering tips, but rather are shallow cup-like members. According to the teachings of this reference, a metering system that includes an aspiration probe 46 is used to collect a metering tip 48 from the interior ring of the illustrated primary

sample supply which is incremented by rotation to a predetermined aspiration position. The metering probe is then used in a conventional manner to aspirate sample from one of the sample containers 19 disposed on the outer ring into the attached tip using the probe. Prior to dispensing fluid onto a slide element E of a "dry" chemistry system portion of the analyzer, the quality of the patient sample can be detected using a spectrophotometer as depicted in Figs. 2A- 4B of the instant reference. Otherwise, the sample is dispensed (e.g., metered) onto the slide element in a conventional manner and the metering tip is then discarded.

Samsoondar describes the general concepts of using a disposable metering tip as a cuvette wherein a first metering tip is sealed and a second tip is used for adding one or more reagents to the confines of the disposable tip along with sample wherein the sealed tip can be placed into a heated cavity to prompt or accelerate a reaction, the results of which can be detected by means of a radiation source/detector pair or a spectrophotometer via "through the tip" analysis.

Corbett describes a holding device that is used for PCR (polymerized chain reaction) so as to perform DNA amplification. The device includes an annular sample holder defined by a plurality of wells that are used to retain a corresponding plurality of pipette tips. The holding device further includes means for heating and cooling the ring as needed so as to allow heating and cooling of contained samples.

The present auxiliary sample handler is designed or configured to interrelate between at least two separate chemistry (analytical) systems of a clinical analyzer. Each of the chemistry systems includes at least one reaction vessel and an analytical instrument that is used to determine a property of a patient sample introduced into the reaction vessel. The analyzer includes a primary sample handling supply that includes a plurality of patient sample containers. According to the present invention, the auxiliary sample handler includes a plurality of first tip retaining stations that are used to retain a first plurality of sealed metering tips. The sealed metering tips contain patient sample in addition to the patient sample already contained within the containers of the primary sample supply wherein the tips can be moved into alignment with an aspiration station to permit patient fluids to be aspirated from the

sealed metering tips. This advantageously enables fluid to be metered from each of the sample containers of both sample supplies for use with the at least two analytical systems and permits asynchronous operation of the analyzer. For example, the primary sample supply can be used in conjunction with a dry chemistry system of the analyzer and the auxiliary sample supply can be used with a wet chemistry system of the analyzer. Moreover, a supply of unsealed metering tips are provided on the auxiliary sample supply, permitting their use with either analytical system in order to convey a reaction fluid, whether patient sample or other such as reagent, for use in each of the analytical systems. Preferably, the unsealed tips are used with a metering system to enable patient sample to be aspirated from the sample containers of the primary sample supply for use with a dry chemistry system while also permitting other tips retrieved from the handler to aspirate reagent or other fluids for use with a wet chemistry system through conveyors aligned with the handler. Preferably, the analyzer detects or senses when a tip has been removed and provides a mechanism in which a new tip is automatically fed to fill the buffer. Such an asynchronous device is not described or suggested by the prior art, either singly or in combination.

Applicants have amended each of independent Claims 1 and 41 to further clarify and distinctly point out these essential differences. Support is provided in the present specification. See for example, page 12, line 20 – page 17, line 5 of the present specification. Therefore, it is respectfully submitted that no new matter has been added. Jacobs et al. fails to describe or suggest anything more than the capability of measuring a metering tip for signal quality. While Samsoondar does describe the general concept of using a metering tip to retain a quality of sample, this reference is instead directed to the use of such a tip being used as a reaction vessel. Such is not the case in the present invention. Nor does Samsoondar teach or describe the general structure of the present invention for a buffer having first and second tip retaining stations are provided for use with at least two chemistry systems of a clinical analyzer. The teachings of Corbett also do not teach the concept of using multiple rings in order to house both sealed metering tips as well as unsealed tips for use with each of at least two chemistry systems of a clinical analyzer.

Because these essential features are missing, it is believed there can be no prima facie obviousness rejection under the Statute with regard to Claims 1 and 41.

Claims 3, 4, 6-14 and 42-43, 46-48, 51-55 and 58-60 are believed allowable for the same reasons since these claims are dependent thereupon. Reconsideration is therefore respectfully requested.

Applicants have added new Claims 74-82 to recite features not previously claimed. Claims 74-79 each relate to Claim 1, et seq. and further recite features relating to detecting when sample tip retaining sections are empty (Claim 74), a removal mechanism when testing is completed, (Claim 75), relationships between the sizes of the metering tip used in the first and second tip retaining stations (Claim 76), the form of analytical systems of the analyzer (Claim 77), and use of the unsealed metering tips (Claims 78 and 79). Claims 80-82 depend from Claim 41 and relate to a tip removal mechanism (Claim 80), the sizing of the metering tips used in the first and second tip retaining stations (Claim 81), and aspects of the combinational analyzer (Claim 82). Support is found for each of these features in the specification. See, for example, the tip detection mechanism disclosed at page 14, lines 26-29, and the tip removal mechanism disclosed at page 17, lines 3-13. Therefore, it is believed no new matter has been added.

Turning to the Section §112 rejections, the Examiner has rejected Claims 1-14, 41-60 under 35 USC 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter regarded as the invention.

Applicants have extensively amended Claims 1 and 41 to positively recite the structural aspects of the sample containers of the auxiliary handler with respect to the analyzer and more particularly those aspects permitting asynchronous operation between multiple analytical systems thereof, through positive recitation of the elements of the analyzer including the primary sample supply and the analytical systems. It is now believed each of these independent Claims 1 and 41 now more to particularly point and distinctly describe the present invention.

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Applicants have further extensively amended the claims based on the above-noted amendments to Claims 1 and 41, specifically Claims 3, 4, 6-14, 42, 43, 45-48, 51-54 and 58-60 having been amended to now comport with these independent claims. Applicants have attempted to insure that the claims, as amended, are sufficiently clear and particularly point out that which is regarded as the present invention. To that end, Claim 6 has been amended cure the informality noted by the Examiner. Claims 44, 51 and 52 are now also believed to be in an allowable form based on the amended versions of Claims 51, 52, as well as those of Claim 41. Reconsideration is respectfully requested.

In summary, it is believed that the above-captioned patent application is now in an allowable condition and such allowance is earnestly solicited.

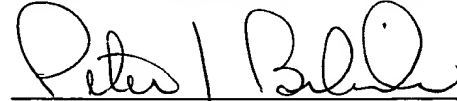
If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicants representative at the telephone number below.

The Director is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

WALL MARJAMA & BILINSKI LLP

By:

A handwritten signature in black ink, appearing to read "Peter J. Bilinski", is written over a horizontal line.

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